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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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OFFICIAL

Serial No.: 09/706,045

Art Unit: 1617

Filed: November 3, 2000

Examiner: E. Webman

For: **POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF**Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

We, Julie Straub and Howard Bernstein, hereby declare that:

1. We are co-inventors of the above-identified application.
2. We conceived of and reduced to practice a method of forming microparticles that contain a diagnostic agent, which was subsequently described in U.S. Patent No. 6,565,885 to Tarara et al. This method involves spray drying a feed stock containing the diagnostic agent, a surfactant and a blowing agent. We conceived of and reduced to practice this method prior to September 29, 1997, as demonstrated by the attached copies of pages from a laboratory notebook (Exhibit A).

3. As noted in Exhibit A, the feed stock to the spray drying apparatus contained ammonium acetate, lecithin, (poly(ethylene glycol)-co-poly(lactide-co-glycolide) (75:25), D,L-

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poly(lactide), and air. This composition was emulsified using a VirTis homogenizer to form an emulsion, which was then spray dried using a small-scale lab spray dryer (see Exhibit A, page 14). The resulting microparticles had diameters ranging from 1-20 microns and were hollow with internal central-like voids containing the air bubble, as demonstrated by transmission electron microscopy (see Exhibit A, page 116). These microparticles were echogenic (see Exhibit A, page 105, injection 7).

4. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further, that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 1-22-04

Julie Straub
Julie Straub

Date: 1-22-04

Howard Bernstein
Howard Bernstein

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